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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,452	06/03/2005	Luca Barella	DSM-01-US	3265

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HOXIE & ASSOCIATES LLC
75 MAIN STREET , SUITE 301
MILLBURN, NJ 07041

EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,452	BARELLA ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0510*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of receipt and entry of the amendment filed on 05/03/2010.

Claims 38-43 have been examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38 stands rejected under 35 U.S.C. 102(b) as being anticipated by Wakayama (Derwent Acc-No 2001-574435 or JP 2001163772 A, see e.g. abstract) for the reasons set forth in the previous OFFICE ACTION which are restated below.

Applicant claims a method comprising administering to any and/or all claimed humans an effective amount of lycopene to reduce androgen signaling whereas androgen signaling is associated with polycystic ovary syndrome.

Wakayama anticipates the claimed invention because Wakayama teaches a method comprising administering to a human an effective amount of lycopene. Moreover, when Wakayama same lycopene as the claimed invention's lycopene is administered in broadly claimed effective amounts to and/or within any and/or all claimed human subjects' body, Wakayama same lycopene as the claimed invention's lycopene would also intrinsically have the same underlining claimed functional effect (i.e. the functional effect to reduce the risk thereof polycystic ovary syndrome associated with androgen signaling) as the claimed invention when administered to

and//or within any and/or all claimed human subjects body. [i.e. please notethat since applicant is claiming the use of lycopene to reduce the incidence of, the administration of lycopene to a human subject would read on treating any and/or all diseases instead of only treating a human subject suffering from the claimed polycystic ovary syndrome associated with androgen signaling because it appears to Examiner that the language "reducing the incidence" means that the claimed human subject does not have to yet have and/or to be suffering from polycystic ovary syndrome] (see, e.g. abstract).

Therefore, the reference is deemed to anticipate the claimed invention.

Applicant's argument has been carefully considered but it is not deemed persuasive. Applicant argument is that Applicant submits the population of individuals which would have received lycopene treatment for senile cataracts as disclosed in Wakayama is not co-extensive with the population which would be at risk for polycystic ovary syndrome, as the population at risk for polyscystic ovary syndrome is substantial younger. However, Examiner maintains that Applicant argument is not found persuasive because as discussed above in Examiner's 35 USC 102(b) rejection since applicant is claiming the use of lycopene to reduce the incidence of, the administration of lycopene to a human subject would read on treating any and/or all diseases instead of only treating a human subject suffering from the claimed polycystic ovary syndrome associated with androgen signaling. Therefore, Wakayama anticipates the claimed invention when Wakayama same lycopene as the claimed invention's lycopene is administered in broadly claimed effective amounts to and/or within any and/or all

claimed human subjects' body, Wakayama same lycopene as the claimed invention's lycopene would also intrinsically have the same underlining claimed functional effect (i.e. the functional effect to reduce the risk thereof polycystic ovary syndrome associated with androgen signaling) as the claimed invention when administered to and//or within any and/or all claimed human subjects body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lorant et al. (US 6623769) in view of Murad (US 5962517) and De Salvert (US 5827520) for the reasons set forth in the previous OFFICE ACTION which are restated below.

Applicant claims a method comprising administering to any and/or all claimed humans an effective amount of lycopene to reduce androgen signaling whereas androgen signaling is associated with polycystic ovary syndrome and further comprising vitamin e and vitamin c whereas the claimed active ingredients of lycopene, vitamin e and vitamin c are administered in various amounts.

Lorant teaches an effective amount of lycopene is orally administered to a subject (i.e. a subject of a woman or male) in need thereof to treat acne [please note

that Applicant readily admits within his specification on page 7 lines 27-29 that acne is a disorder associated with androgen signaling and furthermore please note that since applicant is claiming the use of lycopene to reduce the incidence of, the administration of lycopene to a human subject would read on treating any and/or all diseases instead of only treating a human subject suffering from the claimed polycystic ovary syndrome associated with androgen signaling because it appears to Examiner that the language "reducing the incidence" means that the claimed human subject does not have to yet have and/or to be suffering from polycystic ovary syndrome). Therefore, when Lorant same lycopene as the claimed invention's lycopene is administered in effective amounts to and/or within any and/or all claimed human subjects' body to treat acne whereas acne is also well known to be associated with androgen signaling, Lorant's same lyocopene as the claimed invention's lycopene would intrinsically have the same underlining claimed functional effect as the claimed invention when administered to and/or within any and/or all claimed human subjects' body when treating a disorder associated with androgen signaling such as acne (i.e. the functional effect to reduce the risk thereof polycystic ovary syndrome associated with androgen signaling) (see entire patent including column 3 lines 5-10 and page 7, lines 27-29). Lorant does not expressly teach the combination of lycopene, vitamin e and vitamin c administered to a human subject to reduce androgen signaling whereas androgen signaling is known to be associated with polycystic ovary syndrome.

Murad benefically teaches vitamin E treats disorders associated with androgen signaling such as acne (see entire patent including column 3, lines 1-10).

De Salvert benefically teaches vitamin C treats disorders associated with androgen signaling such as acne (see entire patent including column 4, lines 50-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lorant to include the claimed active ingredients of vitamin E and vitamin C as taught by Murad and De Salvert within Lorant's method teachings because the above combined reference as a whole would create the claimed invention of a method comprising administering to any and/or all claimed human subjects an effective amount of the combination of lycopene, vitamin C and vitamin e to treat a disorder associated with androgen signaling such as acne. Moreover, when claimed invention's combination of lycopene, vitamin C and vitamin E is administered in effective amounts to and/or within any and/or all claimed human subjects' body to treat acne whereas acne is also well known to be associated with androgen signaling, the claimed combination of active ingredients as the claimed invention's combination of active ingredients would intrinsically have the same underlining claimed functional effect as the claimed invention when administered to and/or within any and/or all claimed human subjects' body when treating a disorder associated with androgen signaling such as acne (i.e. the functional effect to reduce the risk thereof polycystic ovary syndrome associated with androgen signaling). Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. to treat acne), in order to form a third composition to be used for the same purpose" Furthermore, the adjustment of other conventional working conditions (e.g.

determining suitable amounts/ranges of each active ingredient administered to human subject and the amounts and times per day the claimed active ingredients are administered), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant's arguments have been carefully considered but they are not deemed persuasive. Applicant argues that it is well known there are many causes of acne, and the population of people who suffer from acne is certainly not co-extensive the population of people who suffer from polycystic ovary syndrome because males may suffer from acne but not all women with acne have polycystic ovary syndrome and not all women with polycystic ovary syndrome have acne. However, Examiner maintains that Applicant argument is not found persuasive because as discussed above in Examiner's 35 USC 103(a) rejection since applicant is claiming the use of lycopene to reduce the incidence of, the administration of lycopene to a human subject would read on treating any and/or all diseases instead of only treating a human subject suffering from the claimed polycystic ovary syndrome associated with androgen signaling because it appears to Examiner that the language "reducing the incidence" means that the claimed human subject does not have to yet have and/or to be suffering from polycystic ovary syndrome. Therefore, when Lorant same lycopene as the claimed

invention's lycopene is administered in effective amounts to and/or within any and/or all claimed human subjects' body to treat acne whereas acne is also well known to be associated with androgen signaling, Lorant's same lyocopene as the claimed invention's lycopene would intrinsically have the same underlining claimed functional effect as the claimed invention when administered to and/or within any and/or all claimed human subjects' body when treating a disorder associated with androgen signaling such as acne (i.e. the functional effect to reduce the risk thereof polycystic ovary syndrome associated with androgen signaling- [also please note that Lorant discloses in column 2 lines 39-46 of its specification as the subject being administered lycopene is a women. Therefore, when Lorant's same lycopene as the claimed invention same lycopene is administered to and/or within a women's body, Lorant's same lyocopene as the claimed invention's lycopene would intrinsically have the same underlining claimed functional effect as the claimed invention when administered to and/or within a women's body such as the underlining functional effect of reducing the incidence of polycystic ovary syndrome in a women.]

Moreover, Applicant argues none of the references teach or suggest lycopene, vitamin E and vitamin C are equivalents, or may be substituted for one another to achieve a common effect. However, Examiner maintains that Applicant argument is not found persuasive because as discussed above in Examiner's 35 USC 103(a) rejection, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lorant to include the claimed active ingredients of vitamin E and vitamin C as taught by Murad and De Salvert within Lorant's method

teachings because the above combined reference as a whole would create the claimed invention of a method comprising administering to any and/or all claimed human subjects an effective amount of the combination of lycopene, vitamin C and vitamin e to treat a disorder associated with androgen signaling such as acne.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655